K112615

OCT 1 1 2011

SECTION 5

Special 510(k) Premarket Notification

Summary of Safety and Effectiveness information

Tornier Inc. Aequalis Ascend Modular Reverse Shoulder System

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) **Device name**

Trade name: **Aequalis Ascend Modular Reverse Shoulder System**
Common name: Shoulder Prosthesis

Classification Number/ Classification name/Product code:

- Shoulder joint metal/polymer non-constrained cemented prosthesis are class II devices under 21 CFR 888.3650 (product code KWT) and are classified by the Orthopedic Devices Panel.
- Shoulder joint metal/polymer semi-constrained cemented prosthesis are class II devices under 21 CFR 888.3660 (product code KWS) and are classified by the Orthopedic Devices Panel.
- Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis are class II devices under CFR 888.3690 (product code HSD) and are classified by the Orthopedic Devices Panel.

2) **Submitter**

Tornier Inc.
7701 France Avenue South; Suite 600
Edina, MN 55435
Registration Number: 9100540

3) **Company contact**

Brahim Hadri
Sr. Regulatory affairs Specialist
7701 France Avenue South, Suite 600
Edina, MN 55435 USA
Telephone: 781-249-8030
Fax: 952-426-7601
Email: bhadri@tornier.com

4) **Classification**

Device class:	Class II
Classification panel:	Orthopedic
Product code:	**KWT; KWS; HSD**

5) **Legally Marketed Device to which Equivalence is Claimed:**

- Tornier Aequalis Ascend Modular Reverse Shoulder System: **K110599**

6) **Device description**

The Aequalis Ascend Modular Reverse shoulder prosthesis is a component of semi-constrained reverse shoulder prosthesis.

The Aequalis Ascend Modular Reverse Shoulder system is supplied in separate sterile packages which will be assembled in the operating room. The components provided are:

- The Modular Reverse Metaphysis and Modular Reverse Assembly Screw
- The Modular Reverse Inserts
- An optional Modular Reverse Spacer and Modular Reverse Spacer Assembly Screw can be used when maximum insert thickness does not achieve sufficient tension.
    - When the Modular Reverse Spacer is implanted, the Modular Reverse Spacer Assembly Screw will be used in place of the Modular Reverse Assembly Screw.

The present device submission corresponds to changes made to the version of the device cleared in 510(k) K110599.

Primary Reverse Shoulder:

The Aequalis Ascend Modular Reverse Metaphysis and Aequalis Ascend Modular Reverse Assembly Screw will mate with the existing; FDA cleared Tornier Aequalis Ascend Modular Anatomic Distal Stem (K102924 and K110865) which, when assembled together with the Aequalis Ascend Modular Reverse Insert, form a complete reverse prostheses. The reverse assembly must be used in association with the Aequalis Reversed or Aequalis Reversed II glenoid implants (K081059).

Conversion Reverse Shoulder:

The Aequalis Ascend Reverse Metaphysis and Aequalis Ascend Modular Reverse Assembly Screw are designed to allow the transformation of the Aequalis Ascend Anatomic shoulder (K102924 and K110865) into an Aequalis Ascend Modular Reverse Shoulder without removal of the Diaphyseal Stem, if the stem is well fixed during revision surgery. The Aequalis Ascend Reverse Metaphysis is a metal component designed to articulate as a reverse prosthesis with a specific polyethylene insert. The metal metaphysis is impacted onto the taper of the Diaphyseal Stem and then secured with the Ascend Modular Reverse Assembly Screw. The screw is tightened until it is firmly seated on the Reverse Metaphysis. A Reverse Spacer can be used when the maximum insert thickness does not achieve sufficient tension. During these situations, after impaction of the Reverse Metaphysis on the Diaphyseal stem, the metal spacer is impacted on the taper of the Reverse Metaphysis and then secured with the Ascend Modular Reverse Spacer Assembly Screw. The screw is tightened until it is firmly seated on the Reverse Spacer.

7) **Materials**

- The Modular Reverse Metaphysis and Modular Reverse Spacer components are manufactured from Titanium according to ASTM F 136 Standard Specification for Wrought Titanium - 6Aluminum - 4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

- The Modular Reverse Assembly Screw and Modular Reverse Spacer Assembly Screw are manufactured from Cobalt Chromium Molybdenum alloy according to ASTM F-1537 Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants

- The Modular Reverse Assembly Screw and Modular Reverse Spacer Assembly Screw include an Ultra High Molecular Weight Polyethylene (UHMWPE) plug. The material of the screws is accordance to ASTM F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants or ISO-5834-2. Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 2: Moulded forms

8) Indications for Use

- The Aequalis Ascend Modular Reverse Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled by:
    - Rheumatoid arthritis
    - Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
    - Correction of functional deformity
    - Fractures of the humeral head
    - Traumatic arthritis
    - Revision of the devices if sufficient bone stock remains
- The Reverse Metaphysis and Assembly Screw or the Reverse Metaphysis, Reverse Spacer, and Reverse Spacer Assembly Screw are indicated for use as components of the Aequalis Ascend Modular Reverse total shoulder replacement and for transformation of the Aequalis Ascend Anatomic shoulder into a reverse shoulder prosthesis without the removal of the Diaphyseal stem during revision surgery for patients with a functional deltoid muscle. The components are permitted to be used in the transformation from anatomic to reverse if:
    - The Diaphyseal stem is well fixed
    - The patient has a functional deltoid muscle
    - The arthropathy is associated with a massive and non-repairable rotator cuff-tear.
- Notes:
    - All components are single use
    - The humeral stem is intended for cemented or cementless use
    - The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

9) Summary of technologies

The modified Tornier Aequalis Ascend Modular Reverse Shoulder System was subjected to non-clinical testing such as fatigue and insert disassembly testing.The results of those non-clinical tests allow us to conclude that the Tornier Aequalis Ascend Modular Reverse Shoulder System described in this submission is substantially equivalent and as safe and effective as the cited predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 1 1 2011

Tornier, Inc.
% Mr. Brahim Hadri
Sr. Regulatory Affairs Specialist
7701 France Avenue South, Suite 600
Edina, Minnesota 55435

Re: K112615
Trade/Device Name: Aequalis Ascend Modular Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: KWS, KWT, HSD
Dated: September 7, 2011
Received: September 8, 2011

Dear Mr. Hadri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112615

Device Name: **Aequalis® Ascend™ Modular Reverse Shoulder System**

Indications for Use

- The Aequalis Ascend Modular Reverse Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled by:
  - Rheumatoid arthritis
  - Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
  - Correction of functional deformity
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  - The Diaphyseal stem is well fixed
  - The patient has a functional deltoid muscle
  - The arthropathy is associated with a massive and non-repairable rotator cuff-tear.
- Notes:
  - All components are single use
  - The humeral stem is intended for cemented or cementless use
  - The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

Prescription Use ____X_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112615